K013994

APPENDIX 4

FEB 01 2002

510(K) Summary

VIEWSEND Medical

Submitted By:	KLT Telecom, Inc. 14080-A Sullyfield Circle Chantilly, VA 20151 Tel. 703.502.1488
Contact Person:	Ken Logsdon, Jr. Director of Programs 703.502.1840
Modified Device Trade Name:	**VIEWSEND Medical**
Unmodified Device Trade Name:	**VIEWSEND Medical Model 1200** (K-962225)
Common Name:	VIEWSEND Medical
Classification:	Unclassified

A. DEVICE DESCRIPTION

When integrated into an appropriate PC-based platform, **VIEWSEND Medical** imaging software contains several modules to enable the medical professional to view, retrieve, store, import, process, collaborate, and transmit medical images in order to render a diagnosis. VIEWSEND Medical software can include teleradiology, telemedicine, and videoconferencing in an open system that runs under the Microsoft Windows 98/2000/NT operating system.

VIEWSEND Medical software is modular and able to provide one or more of the VIEWSEND standard features to match clinical needs – teleradiology, telemedicine, videoconferencing, collaboration, DICOM 3.0, communications, viewer, customizable database, stand-alone or client/server or web-based, compression, or security.

Existing medical films can be digitized, scanned, and stored as DICOM 3.0 images. Communications between systems can be performed over wireless/wired LAN, ISDN, T1, ATM, satellite, or plain old telephone system (POTS). The DICOM option allows for query, retrieve, send, receive, print, or DICOM Dir actions with DICOM 3.0 compliant modalities or servers.

VIEWSEND Medical software allows medical professionals in remote locations to view, discuss and consult on the same images of a patient case file. This can be done with live cameras and scopes or by sending high-resolution files that have been scanned into the remotely located PC.

VIEWSEND Medical software allows images to be sent from the archive files of one machine, and be transported to a different server, so that images from previous examinations may be compared with new more up-to-date images. These stored images can be at the physician request, sent in advance to save time and bandwidth during crucial consultations. Communications between VIEWSEND systems can use industry standard 128-bit encryption, and/or JPEG or JPEG2000 compression.

B. INTENDED USE

When installed on an appropriate PC-based platform, VIEWSEND Medical software is intended to provide the medical professional with the capability to manipulate, annotate, collaborate, and/or transmit medical images in order to render a diagnosis. Options include teleradiology, telemedicine, videoconferencing, communications, viewer, customizable database, DICOM 3.0, stand-alone or client/server or web-based, compression, and/or security.

Communications between systems can be performed over wireless/wired LAN, ISDN, T1, ATM, satellite, and/or plain old telephone system (POTS). The DICOM 3.0 option allows for query, retrieve, send, receive, print, or DICOM Dir actions with DICOM 3.0 compliant modalities or servers.

C. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the modified device are the same as the original device. Incremental revisions to the software have been made.

D. TESTING

Testing of the incremental software revisions followed KLT's normal procedures. A test plan was developed containing a description of relevant test procedures. Test results were documented including what was tested, expected results, whom the test was performed by, which resources used (such as automated test tools).

E. CONCLUSIONS

In summary, KLT has demonstrated that the intended use for **VIEWSEND Medical** is the same as the original device. The technological characteristics have been described in sufficient detail to demonstrate that they are the same as the original device. Therefore, this premarket notification has demonstrated Substantial Equivalence as defined and understood in the Federal Food, Drug, & Cosmetic Act and its amendments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 01 2002

Mr. Ken Logsdon, Jr.
Director of Programs
KLT Telecom, Inc.
14080-A Sullyfield Circle
CHANTILLY VA 20151-1623

Re: K013994
Trade/Device Name: ViewSend Medical
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: II
Product Code: 90 LLZ
Dated: January 10, 2002
Received: January 11, 2002

Dear Mr. Logsdon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013994

Device Name: ViewSend Medical

Indications For Use:

When installed on an appropriate PC-based platform, VIEWSEND Medical software is intended to provide the medical professional with the capability to view, retrieve, store, import, process, collaborate, and/or transmit medical images in order to render a diagnosis. Options allow for teleradiology, telemedicine, videoconferencing, collaboration, DICOM 3.0, communications, viewer, customizable database, stand-alone or client/server or web-based, compression, or security. Communications between systems can be performed over wireless/wired LAN, ISDN, T1, ATM, satellite, and/or plain old telephone system (POTS). The DICOM 3.0 option allows for query, retrieve, send, receive, print, or DICOM Dir actions with DICOM 3.0 compliant modalities or server

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Optional Format 3-10-98)

David G. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013994